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14. ABSTRACT

This report provides a description of the **Year 2** progress made for the project entitled "*Research to Improve Emotional Health and Quality of Life Among Service Members with Disabilities (RESTORE LIVES)*. There are 5 studies being conducted in this project and final study protocols and Institutional Review Board (IRB) approvals have been in place since Year 1. Year 2 has been devoted to subject recruitment, enrollment, retention, follow-up, and data analysis and dissemination activities. Four of the 5 studies have made significant progress in enrolling study subjects. The study entitled "Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans" has continued to experience difficulty in developing and validating a fully functional online platform for this web-based study. Corrective actions for this study have been implemented. Several studies have disseminated early results in peer-reviewed venues, and manuscripts are in progress. Budget expenditures to date are consistent with the approved Statement of Work and milestones.

15. SUBJECT TERMS
Post-traumatic stress disorder, psychotherapy, stress, mild traumatic brain injury, women veterans prevalence

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1.0 Introduction

This report provides a description of the **Year 2** progress made for the project entitled "*Research to Improve Emotional Health and Quality of Life Among Service Members with Disabilities (RESTORE LIVES).*" Included is a description of research accomplishments associated with the individual tasks outlined in the approved Statement of Work. At the broadest level, this project has 5 individual sub-studies with the following research hypotheses and expected results:

Substudy #1. *Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans*

Hypotheses: (i) The web-based ACT program will improve (i) mental health functioning in veterans, as indexed by validated and evidence-based measures of PTSD, anxiety-related distress, depression, and substance abuse; and (ii) quality of life and psychosocial functioning.

Expected Results: Evidence of efficacy for ACT as a non-intrusive, self-paced, web-based therapy for veterans with impaired mental health functioning, distress, and post-deployment adjustment difficulties. These outcomes are expected because the ACT program teaches skills that are broadly applicable to promote resilience and psychological well-being (e.g., mindfulness, acceptance, self-compassion, forgiveness).

Substudy #2. *In-person Accelerated Resolution Therapy (ART) for Psychological Trauma*

Hypotheses: Compared to waitlisted controls, veterans with symptoms of PTSD who receive ART will show greater acute and sustained improvements in self-report measures of PTSD, sleep, depression, anxiety, guilt, hopelessness, and quality of life.

Expected Results: Evidence of efficacy for ART as a novel psychotherapeutic regimen for rapid resolution of symptoms of PTSD.

Substudy #3. *Web-based Mild Traumatic Brain Injury (TBI) Tele-rehabilitation*

Hypotheses: The web-based intervention will be feasible and effective among active duty, veteran, and civilian participants, as defined as follows: (i) participant recruitment and retention will be successful, as evidenced by 80% completion of follow-up; (ii) the web-based intervention will result in increased knowledge of symptoms and self-efficacy, relative to baseline, at immediate follow-up; (iii) relative to the control group, participants will have significantly reduced symptom reporting at 6 month follow-up; (iv) relative to the control group, participants will report significantly enhanced quality of life at 6 month follow-up; and (v) reduction of symptoms will be moderated by presence of PTSD symptoms and degree of self-efficacy.

Expected Results: (i) The web-based protocol for delivering a psycho-educational intervention to reduce post-concussive symptoms following mild TBI will be shown to be feasible and effective; (ii) data obtained will justify funding for a randomized control trial to determine relative efficacy, effectiveness, and cost of various treatment approaches aimed at preventing the endurance and escalation of post-concussive symptoms; (iii) The

VA, military, and private sector will have at their disposal an efficient, inexpensive, portable, user-friendly, and acceptable means to educate and treat individuals suffering with symptoms following mild TBI.

Substudy #4. *Assessment of Base Rates of PTSD, High Risk Behaviors, and Impairment*

Hypotheses: (i) The unmatched count procedure (UCT) will yield more accurate base rates of PTSD, mental health difficulties, and use and abuse of alcohol and controlled substances than those reported in the literature; (ii) Given the stigma associated with endorsing mental health difficulties, underreporting of such behaviors will be greater in active duty relative to veteran samples of military personnel from the Iraq and Afghanistan wars.

Expected Results: Information derived from 1,500 OEF/OIF active duty personnel and veterans will be useful in refining existing early intervention, prevention, and intervention programs, including development of newer programs to more fully meet the needs of active duty military personnel and veterans.

Substudy #5. *Nursing Health Initiative for Empowering Women Veterans*

Hypotheses: This pilot study does not have defined hypotheses, and instead will establish the infrastructure for longitudinal follow-up of a cohort of female veterans with varying levels of stress-induced comorbidities. It is anticipated that the proposed day of recognition and services for female veterans within the Tampa Bay and Sarasota area will result in a wealth of bio-behavioral data on the overall health of female veterans. This venue will be the initial catchment of data collection for what is proposed to be a longitudinal study of the health of female veterans.

Expected Results: (i) Holistic evaluation of life experiences and health status of female veterans; (ii) Appropriate acknowledgement of contributions made by female veterans; (iii) provision of services to female veterans including stress management training, wellness profiling, health risk assessments, screenings for cholesterol, C-reactive protein (CRP), cytokines, stress hormones, nutritional assessment and counseling, massages, facials, pedicures, mental health screening and referral; (iv) job placement services; (v) educational opportunities information and counseling; and (vi) benefits counseling. In addition, this study will collect data on markers of allostasis in these female veterans to help understand their relationships with extreme traumatic experiences, as well as the general health of these women and how they cope with stress.

2.0 Body

This section describes the research accomplishments associated with each task outlined in the approved Statement of Work (SOW). Descriptions are provided overall and for each of the five individual sub-studies.

2.1. Progress for RESTORE LIVES Center as a Whole. Final study protocols were completed in Year 1 along with IRB approvals for all 5 studies. Year 2 has been devoted to subject recruitment, enrollment, retention, follow-up, and data analysis and dissemination activities. Four of the 5 studies have made significant progress in enrolling study subjects. The study entitled "Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans" has continued to experience difficulty in developing and validating a fully functional online platform for this web-based intervention. Description of progress for each of the 5 studies is provided below.

2.1.1. Status of IRB Submissions

All 5 studies have IRB approval with numerous modifications submitted and approved throughout the reporting period, as required by activities of the individual studies.

2.1.2. Participant recruitment. Participant recruitment is ongoing for 4 of the 5 studies, and is summarized below:

Study 1. Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans

No participants have been enrolled to date. This study has experienced considerable difficulty in developing and validating a fully functional online platform to deliver the intervention. Sections 2.1.5 and 2.1.6 provide more detail on the nature of these difficulties and solutions being implemented.

Study 2. In-Person Accelerated Resolution Therapy (ART) for Psychological Trauma

A total of 54 veterans have consented for the trial, of whom, 6 were determined to be clinically ineligible and 48 were enrolled. Thirty nine of the 48 (81.2%) study participants were male. Of the 48 participants enrolled, 11 did not complete treatment or 3-month follow-up. The reasons for early withdrawal from the trial were as follows:

- --- moved away (n=3)
- --- work conflicts (n=2)
- --- too busy (n=1)
- --- did not want to bring up old memories (n=1)
- --- unable to obtain Dr. release (n=1)
- --- referred to private practice (n=1)
- --- unspecified (n=2)

No participants withdrew due to reporting of any adverse effects attributed to study enrollment or treatment with ART.

Study 3. Web-based Mild Traumatic Brain Injury (TBI) Tele-rehabilitation
Participant recruitment began in April, 2012. To date, 622 people have been screened. Of these, 215 met the eligibility criteria and were enrolled in the study (34.5%). Of these, 152 have completed the baseline (89%) evaluation.

Study 4. Assessment of Base Rates of PTSD, High Risk Behaviors
A total of 557 participants have been enrolled in the study. Multiple strategies to reach out to veterans for online enrollment have been and continue to be aggressively pursued.

Study 5. Health Initiative for Empowering Women Veterans
A total of 52 women completed the entire study protocol. Additional female veterans are being recruited through an amended IRB protocol.

2.1.3. Scientific presentations. As data are being accumulated within the individual research studies, dissemination efforts have commenced. Below is a listing of major scientific presentations during the performance period.

Study 2. In-Person Accelerated Resolution Therapy (ART) for Psychological Trauma

Kip KE, Sullivan KL, Kadel RP, Elk CA, Shuman A, Hernandez DF, Diamond DM, Girling SA, and Rosenzweig L. Accelerated Resolution Therapy (ART) for Brief Treatment of Combat-Related Psychological Trauma. Poster presentation at the 2012 Military Health System Research Symposium, August 15, 2012, Ft. Lauderdale, FL.

Study 5. Health Initiative for Empowering Women Veterans

Rossiter, A.G., Sahebzamani, F.M., Webb, M.S. **&** Groer, M.W. (2012, June). *Relationship of Sexual Trauma with the Health of Women Veterans*. Poster presentation at the Psychoneuroimmunology Research Society's 19th Annual Scientific Meeting, San Diego, CA.

Groer, M.W., Radford. A., Williams, S. N**. &** Kane, B. (2012, June). *Relationships of Toxoplasma gondii antibody titers and dysphoric moods in female veterans.* Poster presentation at the Psychoneuroimmunology Research Society's 19th Annual Scientific Meeting, San Diego, CA.

In addition, draft manuscripts have been developed for Study 3: *Web-based Mild Traumatic Brain Injury (TBI) Tele-rehabilitation* and Study 4: *Assessment of Base Rates of PTSD, High Risk Behaviors*.

2.1.4. Grant development. Based on the protocol developed and initial results observed for Study #2, a large NIH R-01 grant (clinical trial) was submitted in June 2012 to evaluate the efficacy of Accelerated Resolution Therapy (ART) for treatment of PTSD secondary to sexual abuse. This grant, if funded, will enroll both civilians and veterans with PTSD secondary to sexual abuse, and will include oversampling of males.

Trial of Accelerated Resolution Therapy for Sexual Trauma
1R01MH100050-01 (Kip PI) April 2013 – March 2018
Submitted to National Institute of Mental Health

2.1.5. Unexpected problems. In Year 1, the time required to obtain multiple IRB approvals (e.g. (SUNY, USF, TATRC) was challenging and resulted in project delays. Nonetheless, study development activities have been able to proceed, and with the no cost extension approved for the project, significant progress is being made. The primary exception to this is Study #1: *Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans*" which has experienced difficulty in developing and validating a fully functional online platform for this web-based study. See description in Section 2.2.1.

2.1.6. Solutions to unexpected problems. Solutions to unexpected problems are related to Study #1: *Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans*", as described in section 2.2.1.5.

2.1.7. Serious Adverse Events. None observed or reported to date.

2.2. Progress for Individual Studies Within the RESTORE LIVES Center
This section describes progress for each individual study of the project.

2.2.1. Study 1. Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans

2.2.1.1. Protocol completion and revisions. Previously approved and operational.

2.2.1.2. IRB submissions and revisions. Previously approved and operational.

2.2.1.3. Participant recruitment. None to date.

2.2.1.4. Unexpected problems. As stated above, this study has experienced difficulty in developing and validating a fully functional online platform for the web-based intervention. As background, this study entails the development of 10 modules of an ACT treatment protocol in an online format based on a previously published workbook. To date, online content including video clips, audio recordings, graphics, and presentation slides have been developed for all 10 modules. The principal problem is a lack of success in hosting a functional platform to deliver all of the content (treatment) without errors (e.g. site shuts down, inappropriate branching, etc.).

The Principal Investigator of this study, Dr. John Forsyth from the University at Albany, SUNY, subcontracted the Information Technology (IT) portion of this project to a private company in the United Kingdom named Panoetic (http://panoetic.com/). Despite months of effort, Panoetic has been unsuccessful in developing, beta-testing, and revising the code required for delivery of the treatment program. The time period permitted by Dr. Forsyth for successful completion of this critical task has been very lengthy. Thus, the project in its current stage suffers from lack of

adequate IT expertise to deliver the treatment protocol, and a lack of oversight in management of subcontractors.

2.2.1.5. Solutions to unexpected problems. Dr. Edward Hickling has replaced Dr. Forsyth as PI for the study. In addition, project personnel have been re-assigned and are now working directly as USF employees under the direction of Drs. Hickling and Kip. The IT vendor, Panoetic, has been terminated and a subcontract with a group in India is in progress. In addition, the study hired an IT specialist, Jake Stookey, as a USF employee to assist with development of the online platform. Given the above actions and difficulties experienced to date, the goal is to develop, pilot test, and revise a fully functional online platform for delivery of the ACT intervention. Moreover, this platform will be "generic" in the sense of being modifiable for other online treatment protocols. These materials will be delivered to TATRC at the close of the project.

2.2.1.6. Status of scheduled deliverables.

Deliverable	**Due Date**	**Status**
1. Seek all IRB approvals: 2. Extra step added: Scientific Review required 3. University of South Florida (USF), including affiliated VA and veteran groups 4. TATRC - USAMRMC ORP HRPO	December 23, 2010	1)SUNY IRB complete 2)Scientific review complete 3) USF IRB complete 4) TATRC – Approved on 8/9/2011
5. Qualtrics Contract/ Site set-up	June 1, 2011	Transfer Contract to USF and pay second installment complete. Site functioning and interactive with initial phase of online product.
6. IT web design and programming	March 1, 2011	Researched /decided on final IT options, interviewed design firm.
7. Hire on-site Information Technology Specialist to support module creation and audio-visual editing.	May 9, 2011	ITS hired and started.
8. Panoetic Contract / Initial set-up	May 26, 2011	Contract accepted and first invoice paid by USF.
9. Meetings with Panoetic to establish study needs in relation to technical organization of site.	June 2 and 7, 2011	Established communication protocols and discussed user format to create site design parameters.
10. Appoint Research Assistants to maintain filming and editing	March 8, 2011	Two RAs and one GA assigned to learn editing processes and to continue to execute as needed

consistency		through end of summer 2011.
11. Module Writing	June 8, 2011	Modules 1-4 completed. Modules 5,6 in editing Modules 7,8,9,10 in progress
12. Module Filming	March, 2011 begin	Modules 1-4 completed, in editing. Balance of modules scheduled through August 2011.
13. Grant Meetings	March - June, 2011	In progress weekly. Now focused on Module creation, filming and IT collaboration
14. Marketing contacts	August 2011	Ongoing. Initial key contacts set.
15. Establish Web Host, secure site and domain name registry	June 27, 2011	Approval of site by Panoetic in progress
16. Begin participant tracking organization and payment process	June 1, 2011	In process of establishing payment system through Research Foundation and discussing tracking options with Panoetic and Qualtrics
17. Online Study up and running for test purposes	August 15, 2011	Portions of the site had been online for testing purposes, but multiple technical and personnel issues have delayed the startup of the study. Site is currently not functioning online.
18. End relationship with Panoetic, web design firm	September 2012	Website passwords and codes retrieved from Panoetic in order to provide them to future web design firm that is hired.
19. Recruit study participants		No participants have yet been recruited.
20. Collect research data		No data have been collected.
21. Data entry/management		No data entry/management has occurred.
22. Data analysis		The study has not formally started, thus, there are no data to analyze.
23. Develop presentations, reports and manuscripts		Not applicable at this time.
24. Disseminate study results		Not applicable at this time.

2.2.2. Study 2. In-person Accelerated Resolution Therapy (ART) for Psychological Trauma

2.2.2.1. Protocol completion and revisions. Previously approved and operational.

2.2.2.2. IRB submissions and revisions. Previously approved and operational.

2.2.2.3. Participant recruitment. A total of 54 veterans have consented for the trial, of whom, 6 were determined to be clinically ineligible and 48 were enrolled. Thirty nine of the 48 (81.2%) study participants were male. Of the 48 participants enrolled, 11 did not complete treatment or 3-month follow-up. The reasons for early withdrawal from the trial were as follows:

- --- moved away (n=3)
- --- work conflicts (n=2)
- --- too busy (n=1)
- --- did not want to bring up old memories (n=1)
- --- unable to obtain Dr. release (n=1)
- --- referred to private practice (n=1)
- --- unspecified (n=2)

No participants withdrew due to reporting of any adverse effects attributed to study enrollment or treatment with ART.

2.2.2.4. Unexpected problems. None to date.

2.2.2.5. Solutions to unexpected problems. N/A.

2.2.2.6. Status of scheduled deliverables.

Deliverable	**Due Date**	**Status**
Finalize study protocol and informed consent	Dec 23, 2010	Completed
IRB approval	Dec 23, 2010	Completed
Develop/finalize case report forms and MOP	Dec 23, 2010	Completed and pilot-tested.
Train ART therapists	Dec 23, 2010	Twenty (20) therapists were trained and certified in the greater Tampa Bay Area. In addition, 12 therapists received training on military terminology and culture, as well as formal certification as professional traumatologists.
Develop recruitment materials	March 23, 2011	Completed
Recruit study participants	Dec 23, 2012	In progress

Collect research data	Dec 23, 2012	In progress
Data entry/management	March 31, 2013	In progress
Data analysis	April 30, 2013	In progress
Develop presentations, reports, and manuscripts	April 30, 2013	In progress
Disseminate study results	April 30, 2013	In progress

2.2.3. Study 3. Web-based Mild Traumatic Brain Injury (TBI) Tele-rehabilitation

2.2.3.1. Protocol completion and revisions. Previously approved and operational.

2.2.3.2. IRB submissions and revisions. Previously approved and operational.

2.2.3.3. Participant recruitment. Participant recruitment began in April, 2012. To date, 622 people have been screened. Of these, 215 met the eligibility criteria and were enrolled in the study (34.5%). Of these, 152 have completed the baseline (89%) evaluation.

2.2.3.4. Unexpected problems. None other than the delay in getting VA approval which was obtained late in Year 1.

2.2.3.5. Solutions to unexpected problems. N/A

2.2.3.6. Status of scheduled deliverables.

Deliverable	**Due Date**	**Status**
Finalize study protocol and informed consent	December 23, 2010	Completed
Write IRB proposals and seek approvals at the and University of South Florida and Tampa VA R&D	March 23, 2011	Completed
Recruitment and training of post-doctoral fellow	March 23, 2011	Completed; Postdoc Fellow began work on 9/12/2011; she is finishing 9/7/2012. Fortunately, DVBIC is donating someone to take over some of those responsibilities.
Web development and testing	June 23, 2011	Completed.
Subject recruitment and treatment implementation	December 23, 2011	Ongoing (subject recruitment began in April, 2012). There have been 622 people screened, as of 8/30/2012. Of those, there are 215 people who met the

		eligibility criteria and were enrolled in the study (34.5%). Of these, 152 completed the baseline (89%) evaluation.
Obtain Post-Treatment PCS and satisfaction data	December 23, 2011	Ongoing
Obtain 6-month follow-up PCS data	December 23, 2012	Not applicable at this time
Data cleaning, preliminary data analysis	December 23, 2012	Ongoing
Refinement of treatment for future trial	December 23, 2012	Not applicable at this time
Plan and write funding proposal for randomized controlled trial	March 30, 2013	Not applicable at this time
Disseminate study results and feedback to DoD	March 30, 2013	Not applicable at this time

2.2.4. Study 4. Assessment of Base Rates of PTSD, High Risk Behaviors

2.2.4.1. Protocol completion and revisions. Previously approved and operational.

2.2.4.2. IRB submissions and revisions. Previously approved and operational.

2.2.4.3. Participant recruitment. A total of 557 participants have been enrolled in the study. Multiple strategies to reach out to veterans for online enrollment have been and continue to be aggressively pursued.

2.2.4.4. Unexpected problems. One unanticipated problem occurred, which was reported to both the University at Albany, SUNY and the University of South Florida Institutional Review Boards (IRBs). On Monday, August 20, 2012 it was discovered that the payment mechanism in the electronic survey was not working. A total of approximately 28 participants were not directed to the payment page. Approximately 11 of these participants contacted project staff and were sent checks. Approximately 17 people did not contact project staff and therefore were not compensated for their survey completion. On Thursday, August 23, 2012, the UAlbany IRB informed the study staff that that a participant had filed a complaint about not receiving payment for participating in the online survey. That participant was paid the same day. The source of the problem was identified and fixed by a newly hired IT professional.

2.2.4.5. Solutions to unexpected problems. Rapid response to all comments received from the respective IRBs.

2.2.4.6. Status of scheduled deliverables.

Deliverable	**Due Date**	**Status**
1) Seek all IRB approvals: 2) Extra step added : Scientific	December 23, 2010	1) SUNY IRB complete 2) Scientific review complete

Review required 3) University of South Florida, including affiliated VA and veteran groups 4) TATRC 1st submission 5) TATRC sent amendments back to USF/SUNYA 6) Final re-submission approval to TATRC	September 2011	3) USF IRB complete 4) TATRC 1st submission complete 5) SUNY 2nd amendment 8/23/11 through September 2011
7) Qualtrics Contract	June 1, 2011-September 2011	Site functioning and interactive with survey material
8) IT web design and programming	March 1, 2011-September 2011	Panoetic, web design firm, began delivery of milestones. Coordinated design with Qualtrics and SUNYA.
9) Hire on-site Information Technology Specialist to support module creation and audio-visual editing	May 9, 2011-September 2011	A new ITS specialist hired
10) Panoetic Contract	May 26, 2011	Second invoice/installment paid by USF based on deliverables
11) Meetings with Panoetic to establish study needs in relation to technical organization of site.	June-September 2011	Ongoing discussions regarding user format and site design parameters
12) Update UCT questions based on pilot data of active duty service members (independent pilot project as part of a student dissertation at SUNYA).	July 2011	Completed.
13) Grant Meetings	March – Sept. 2012	In progress weekly.
14) Marketing	August-Sept. 2012	Ongoing.
15) Establish Web Host, secure site and domain name registry	June 27, 2011-September 2011	Site testing phase. Domain names were purchased and integrated and in active use on website
16) Begin participant tracking organization	June 1, 2011-September 2011	Discussion regarding tracking options with Panoetic and Qualtrics
17) Set up payment process with Research Foundation	September 2011	Participant payment process approved and established through Research Foundation
18) Write Web Content	August-September 2011	Created written content for website and delivered to

		Panoetic
19) Hire additional staff to support project milestone timeline	September 2011	Two graduate assistants and one outside staff hired and started to assist for coming year
20) Online Study up and running for test purposes	August 15, 2011	Continuing to update and improve as needed. Online recruitment was delayed
21. Recruit study participants	March 2012 – December 2012	Participants are being recruited via multiple channels of online recruitment (e.g., email, Facebook, Twitter)
22. Collect research data	March 2012- December 2012	Data are being collected through Qualtrics.
23. Data entry/management	March 2012- February 2013	Data is downloaded and managed initially through Microsoft Excel and then transferred to the SPSS statistical program
24. Data analysis	March 2013	Study personnel have begun to examine preliminary data collected thus far in the SPSS statistical program
25. Develop presentations, reports and manuscripts	March 2013	Initial discussions regarding how to present preliminary data in the coming months
26. Disseminate study results	April 2013	Has not yet occurred.
27. End relationship with Panoetic, web design firm	September 2012	Website passwords and codes retrieved from Panoetic and provided to new IT consultant hired to maintain website
28. Hire new IT consultant	September 2012	Consultant based out of Rensselaer Polytechnic Institute was hired to fix problems on website and take over technical maintenance of website

2.2.5. Study 5. Health Initiative for Empowering Women Veterans

2.2.5.1. Protocol completion and revisions. Previously approved and operational.

2.2.5.2. IRB submissions and revisions. Previously approved and operational.

2.2.5.3. Participant recruitment. A total of 52 women completed the study protocol. Additional female veterans are being recruited through an amended IRB protocol.

2.2.5.4. Unexpected problems. None other than the enrollment of 52 women at the 1-day recognition and appreciation event which was lower than the target of 200 female veterans.

2.2.5.5. Solutions to unexpected problems. The protocol has been amended with approval for recruitment of additional women.

2.2.5.6. Status of scheduled deliverables.

Deliverable	**Due Date**	**Status**
Day of recognition	November 12, 2011	Completed
Collect research data	December 23, 2011	Initial data collection has been completed
Perform biomarker analyses	March 23, 2012	All initial data collected have been analyzed
Setup and manage referral system	January 23, 2012	All veterans received personal reports of data and referrals were suggested
Data entry/management	June 23, 2012	Completed for all initial data collected
Data analysis	November 30, 2012	Additional analyses are in progress
Develop presentations, reports and manuscripts	January 30, 2013	In progress. Two posters presented at the Psychoneuroimmunology Research Society.
Disseminate study results	January 30, 2013	Manuscript in preparation; additional manuscripts planned by women's health research group
Continue enrollment	January 30, 2013	Email sent to all women veterans on campus in July, 2012, and again in Sept, 2012

3.0 Key Research Accomplishments

- **Substudy #1**. **Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans.** All modules have been completed. A new IT firm is being hired to develop a fully operational online platform to deliver the ACT intervention.

- **Substudy #2**. **In-person Accelerated Resolution Therapy (ART) for Psychological Trauma.** A total of 54 veterans consented for the trial, of whom, 6 were determined to be clinically ineligible and 48 were enrolled. An interim analysis indicates that ART is effective in reducing symptoms of PTSD among veterans in a brief treatment period. The interim results were disseminated at the 2012 Military Health System Research Symposium, August 15, 2012, Ft. Lauderdale, FL. The full citation is listed below and the poster is provided as an appendix.

  Kip KE, Sullivan KL, Kadel RP, Elk CA, Shuman A, Hernandez DF, Diamond DM, Girling SA, and Rosenzweig L. Accelerated Resolution Therapy (ART) for Brief Treatment of Combat-Related Psychological Trauma. Poster presentation at the 2012 Military Health System Research Symposium, August 15, 2012, Ft. Lauderdale, FL.

- **Substudy #3**. **Web-based Mild Traumatic Brain Injury (TBI) Tele-rehabilitation.** Participant recruitment began in April, 2012. To date, 622 people have been screened. Of these, 215 met the eligibility criteria and were enrolled in the study (34.5%). Of these, 152 have completed the baseline (89%) evaluation. A manuscript is in progress on the early results.

- **Substudy #4**. **Assessment of Base Rates of PTSD, High Risk Behaviors.** A total of 557 participants have been enrolled in the study. A manuscript is in progress on the early results.

- **Substudy #5**. **Health Initiative for Empowering Women Veterans.** A total of 52 women completed the entire study protocol. Additional female veterans are being recruited through an amended IRB protocol. Multiple presentations have been made, as listed below.

  Rossiter, A.G., Sahebzamani, F.M., Webb, M.S. **&** Groer, M.W. (2012, June). *Relationship of Sexual Trauma with the Health of Women Veterans*. Poster presentation at the Psychoneuroimmunology Research Society's 19th Annual Scientific Meeting, San Diego, CA.

  Groer, M.W., Radford. A., Williams, S. N**. &** Kane, B. (2012, June). *Relationships of Toxoplasma gondii antibody titers and dysphoric moods in female veterans.* Poster presentation at the Psychoneuroimmunology Research Society's 19th Annual Scientific Meeting, San Diego, CA.

4.0 Reportable Outcomes

- **Substudy #2**. **In-person Accelerated Resolution Therapy (ART) for Psychological Trauma.** Significant news coverage on initiation of interim results of this study.

  Submission of NIH grant application based on the protocol developed and therapists trained for Substudy #2:

  Trial of Accelerated Resolution Therapy for Sexual Trauma
  1R01MH100050-01 (Kip PI) April 2013 – March 2018
  Submitted to National Institute of Mental Health

5.0 Conclusion

Significant progress has been achieved in Year 2 in terms of subject recruitment, enrollment, retention, follow-up, and data analysis and dissemination activities. Four of the 5 studies have enrolled a large number of study subjects. The study entitled "Modular Online Acceptance & Commitment Therapy (ACT) Intervention for OIF/OEF Veterans" has continued to experience difficulty in developing and validating a fully functional online platform for this web-based study. Corrective actions for this study have been implemented. Several studies have disseminated early results in peer-reviewed venues, and manuscripts are in progress. Results from all studies have high relevance and potential clinical and scientific application to service members and veterans who have served in combat-related missions and assignments, particularly with respect to psychological difficulties and related comorbidities. Moreover, this research has high emphasis on reaching out to service members and veterans not currently in the conventional treatment system, including by use of web-based therapies. Thus, the interventions being evaluated offer the potential to significantly improve access to mental health care.

6.0 References

None.

7.0 Appendices

Poster presentation. Kip KE, Sullivan KL, Kadel RP, Elk CA, Shuman A, Hernandez DF, Diamond DM, Girling SA, and Rosenzweig L. Accelerated Resolution Therapy (ART) for Brief Treatment of Combat-Related Psychological Trauma. Presented at the 2012 Military Health System Research Symposium, August 15, 2012, Ft. Lauderdale, FL.

See appendix at the end of this document.

8.0 Quarterly, Annual, and Cumulative Budget Report Summary

1. Award No. W81XWH-10-1-0712

3. Reporting period from June 8, 2012 to September 7, 2012 (Quarter #8)
   Reporting period from September 8, 2011 to September 7, 2012 (Annual)
   Reporting period from September 8, 2011 to September 7, 2012 (Annual)

4. PI: Kevin E. Kip, Ph.D., FAHA 5. Telephone No. (813) 974-9266

6. Institution: University of South Florida, College of Nursing

7. Project Title: Research to Improve Emotional Health and Quality of Life among Service Members with Disabilities (RESTORE LIVES)

8. Award expenditures to date (as applicable):

Accelerated Resolution Therapy (ART) For Brief Treatment of Combat-Related Psychological Trauma

Kevin E. Kip, Ph.D., Kelly L. Sullivan, Ph.D., Rajendra P. Kadel, MS, Carrie A. Elk, Ph.D., Amy Shuman, MSW,

Diego, F. Hernandez, Psy.D., David M. Diamond, Ph.D., Sue Ann Girling, BSAS, and Laney Rosenzweig, LMFT

Introduction

Post-traumatic Stress Disorder (PTSD) is a disabling anxiety disorder that is highly prevalent among members of the Armed Services who have served in combat operations.[1] Evidence-based cognitive behavioral therapies for PTSD include Cognitive Processing Therapy (CPT), Prolonged Exposure (PE) therapy, and Eye Movement Desensitization and Reprocessing (EMDR) which lead to clinically improved outcomes in ~50% of all treated cases[2-4] and typically require between 8-15 treatment sessions. Pharmacological approaches to treating PTSD do not resolve the cause of PTSD and patients frequently experience side effects and withdrawal. Accelerated Resolution Therapy (ART) is a new exposure-based therapy that uses eye movements and is designed to be brief (i.e. 1-5 treatment sessions).

Objectives/Aims

- By use of a randomized controlled trial, to evaluate ART versus an Attention Control (AC) regimen as a brief treatment for combat-related symptoms of PTSD and related comorbidities. This included evaluation of initial treatment efficacy and safety.

Methods

- Veterans with previous combat-related exposure and trauma were recruited from the greater Tampa Bay, FL area.
- Intake assessment was based on the 17-item PTSD Checklist Military version (PCL-M);[5] and 125-item (yes/no) Psychiatric Diagnostic Screening Questionnaire (PDSQ)[6]
- All therapists were formally trained and certified in ART.
- **Inclusion Criteria**:

(i) Age 18 years or older
(ii) U.S veteran of any prior deployment(s) with recruitment emphasis of those who served in Iraq and/or Afghanistan.
(iii) Symptoms indicative of PTSD (PCL-M score ≥ 40) and other evidence derived from intake assessment
(iv) Denial of suicidal or homicidal ideation
(v) No evidence of psychotic behavior or otherwise being in psychological crisis
(vi) Ability to read and speak English (survey questions)
(vii) Veterans with previous treatment for symptoms of PTSD, yet with residual symptoms that met inclusion criteria upon screening, were eligible for the study

- **Exclusion Criteria**:

(i) Brain injury prohibiting speech, writing, and purposeful actions
(ii) Major psychiatric disorder primary to symptoms of psychological trauma that would interfere with treatment
(iii) Current treatment for substance abuse
(iv) Previous diagnosis of eye movement disorder that would interfere with ART (e.g. amblyopia)
(v) Medical condition deemed to place individual at high risk due to a potential heightened emotional reaction (e.g. previous heart attack, seizure disorder)

Elements of ART Sessions

Demonstration of ART by Dr. Carrie Elk (USF College of Nursing) to a reporter from the Tampa Tribune.

http://www2.tbo.com/news/breaking-news/2011/may/23/ptsd-treatment-in-a-day-ar-208993/

By protocol, the ART sessions consisted of:

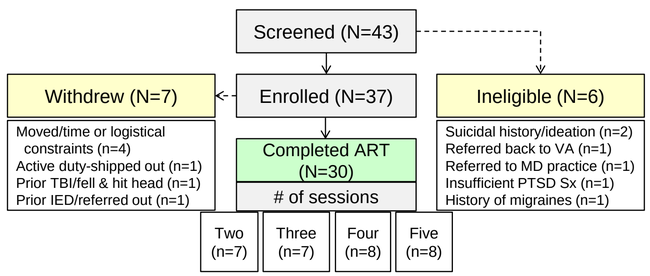
1. Minimum of 1 and maximum of 5 treatment sessions (median = 4), each approximately 60 to 90 minutes in length
2. Assessment of Subjective Units of Distress (SUDS)-10-point scale
3. Discussion with veteran on intended use of Voluntary Image Replacement for distressing scene(s) to be processed (treated)
4. Use of eye movements to process out anxiety and/or body sensations associated with recall of the traumatic memory(ies)
5. Therapist-directed implementation of a creative intervention (from the ART manual) to achieve the Voluntary Image Replacement
6. Attempted recall of original distressing scene versus new scene to assess treatment response to the Voluntary Image Replacement
7. Closure assessment, to include discussion of any future traumatic memories to be treated in subsequent ART sessions
8. Session closeout assessment of SUDS on 10-point scale

Elements of AC Sessions

Subject selection of either Fitness Assessment and Planning or Career Assessment and Planning:

1. Fitness (2 sessions): Measurement of body fat, flexibility, and anthropometrics, followed by setting of fitness goals and plans
2. Career (2 sessions): Career goal setting and planning based on the 48-item Career Planning Scale (Liptak, JJ)

Results



Mean = 3.6, Median = 4 sessions

Results

Demographic and Presenting Characteristics

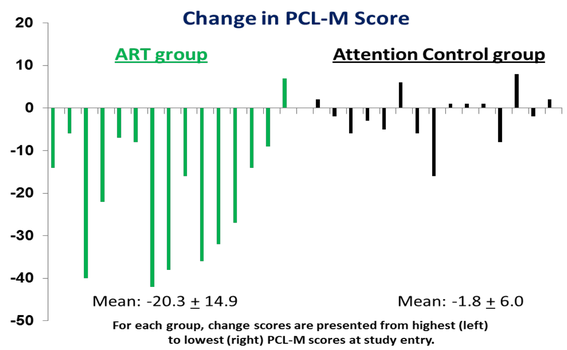
Characteristic	All (n=37)	ART (n=18)	AC (n=19)	P-value
Age in years (mean ± SD)	39.5 ± 11.6	38.7 ± 11.0	40.3 ± 12.3	0.67
Female gender (%)	24.3	27.8	21.1	0.71
Race (%)				0.86
White	75.7	77.8	73.7	
African-American	16.2	16.7	15.8	
Other	8.1	5.6	10.5	
Hispanic ethnicity (%)	16.2	27.8	5.3	0.09
PCL-M Score (mean ± SD)	58.2 ± 16.6	59.6 ± 16.2	56.9 ± 17.3	0.63
PDSQ T-score (mean ± SD)	55.4 ± 11.1	55.2 ± 9.3	55.7 ± 12.8	0.89
Branch of service – Army (%)	51.4	66.7	36.8	0.10
4 or more overseas tours (%)	30.6	29.4	31.6	1.0
Primary deployment(s) (%)				0.54
Iraq	48.7	55.6	42.1	
Afghanistan	13.5	16.7	10.5	
Other	37.8	27.8	47.4	
Longest deployment (months)	16.0 ± 12.9	17.7 ± 15.8	14.5 ± 9.6	0.46
≥5 traumatic memories (%)	45.9	55.6	36.8	0.11
On disability for PTSD/MH (%)	48.7	61.1	36.8	0.19
Trauma-related guilt (%)	83.8	89.5	77.8	0.40

PDSQ: Psychiatric Diagnostic Screening Questionnaire; MH: mental health

Pre/Post Differences in Symptom Measures by Random Assignment

Measure	ART (n=15)	AC (n=15)	Effect Size	P-Value[1]	P-Value[2]
PTSD Checklist (PCL-M)	-20.3 ± 14.9	-1.8 ± 6.0	1.27	0.0003	0.003
Brief Symptom Inventory	-17.1 ± 17.4	-5.4 ± 14.7	0.69	0.06	0.05
Depression (CES-D)	-12.4 ± 13.6	0.9 ± 7.7	1.04	0.003	0.007
Cognitive Anxiety (STICSA)	-9.1 ± 7.1	-0.9 ± 3.9	1.17	0.0008	0.001
Pittsburgh Sleep Quality Index	2.6 ± 5.1	-0.3 ± 1.8	0.75	0.07	0.16
Trauma Related Growth Inv.					
Global Guilt	3.9 ± 5.0	-1.4 ± 1.4	1.17	0.001	0.002
Distress	7.3 ± 3.3	-1.8 ± 4.1	1.23	0.0003	0.009
Guilt Cognition	17.1 ± 24.5	-0.9 ± 15.5	0.81	0.02	0.13
Self-Compassion Scale	15.6 ± 22.6	-0.2 ± 9.9	0.84	0.02	0.09
Aggression Questionnaire	-12.6 ± 19.7	-1.7 ± 8.8	0.68	0.07	0.23
Alcohol Use (AUDIT)	-2.1 ± 0.6	-0.7 ± 3.1	0.48	0.19	0.83

STICSA: State-Trait Inventory for Cognitive and Somatic Anxiety; AUDIT: Alcohol Use Disorder Identification Test. [1]Unadjusted P-value. [2]P-value adjusted for pre-treatment symptom score, Hispanic ethnicity, branch of service, primary deployment location, disability for PTSD/MH.



Results

Clinical Interpretation of Treatment Effects

PCL-M: Reduction of 10 points or more represents clinically meaningful Improvement[7]
ART Group: 10 of 15 subjects with response (66.7%)
AC Group: 1 of 15 subjects with response (6.7%)

CES-D: Score of 16 or higher is suggestive of depression[8]
ART Group: 7 of 11 subjects (63.6%) with CES-D score ≥16 at entry had a score below 16 after ART
AC Group: 2 of 13 subjects (15.4%) with CES-D score ≥16 had a score below 16 after the AC regimen

STICSA: Score of 43 or higher is indicative of clinical anxiety[9]
ART Group: 5 of 7 subjects (71.4%) with STICSA score ≥43 at entry had a score below 43 after ART
AC Group: 2 of 7 subjects (28.8%) with STICSA score ≥43 had a score below 43 after the AC regimen

No study-related serious adverse effects were reported

Conclusions

- ART (2-5 treatment sessions) was superior to an Attention Control regimen in reducing symptoms of PTSD, depression, and anxiety among veterans with combat-related psychological trauma.
- ART was associated with significant improvements in trauma related growth (reduced guilt and distress).
- No consensus as to specific therapeutic role of eye movements, and 3-month follow-up results (sustainability) are pending.
- Given short treatment duration of ART and very large clinical burden of treatment of PTSD being experienced from the wars in Iraq and Afghanistan, future controlled studies versus CPT and PE are warranted.

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